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(54) **PREVENTING INADVERTENT CHANGES IN AMBULATORY MEDICAL DEVICES**

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(58) **Field of Classification Search**

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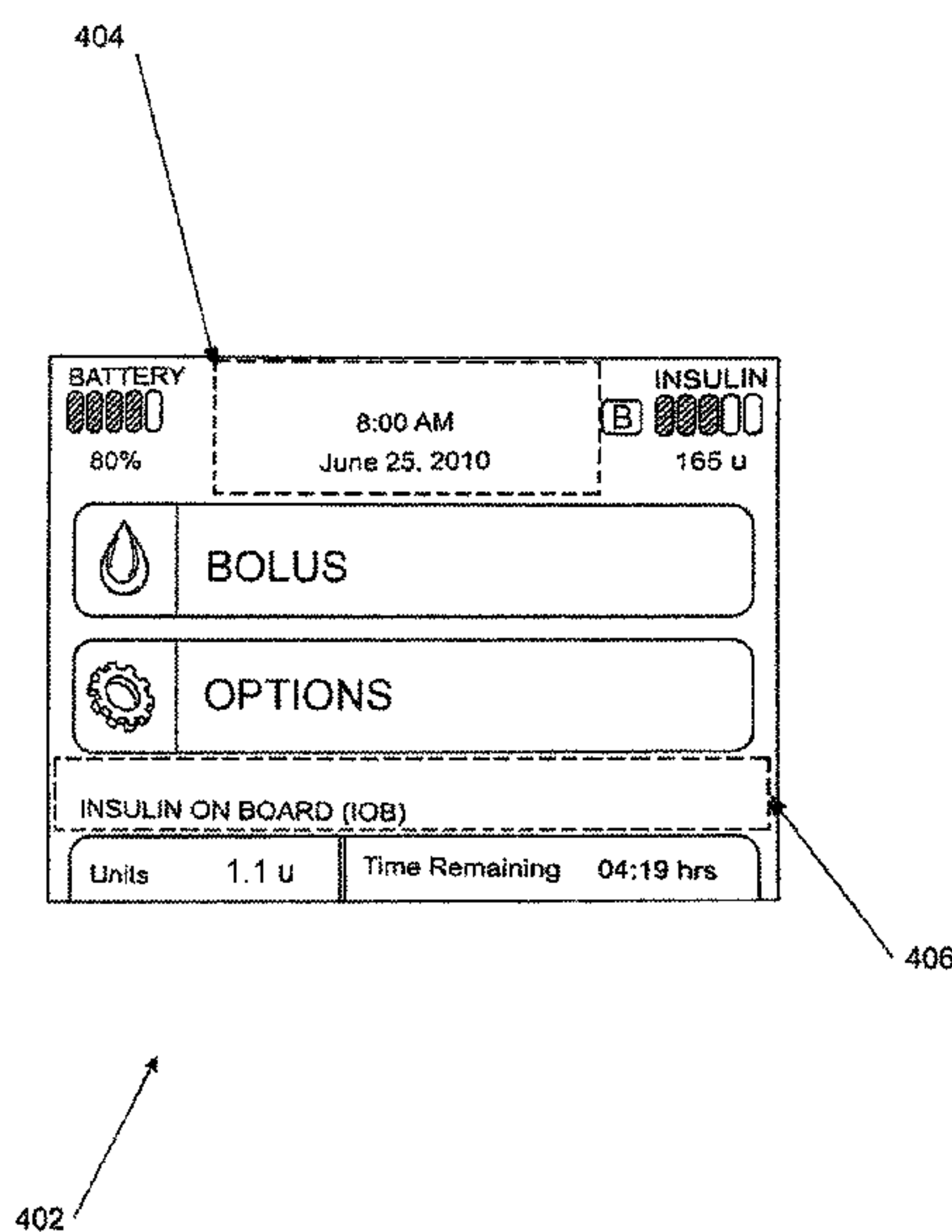
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(57) **ABSTRACT**

A portable medical device is operated in an active mode in which the device receives a user input at an input interlace and provides the received user input to a processor of the device. The active mode is terminated and the device is operated in a safe mode, in which the received user input is not provided to the processor and/or one or more device function is disabled, in response to determining that the received user input was received in an out of bounds region of the input interface. The safe mode is terminated in response to receiving a predetermined user input comprising an activation input.

20 Claims, 7 Drawing Sheets



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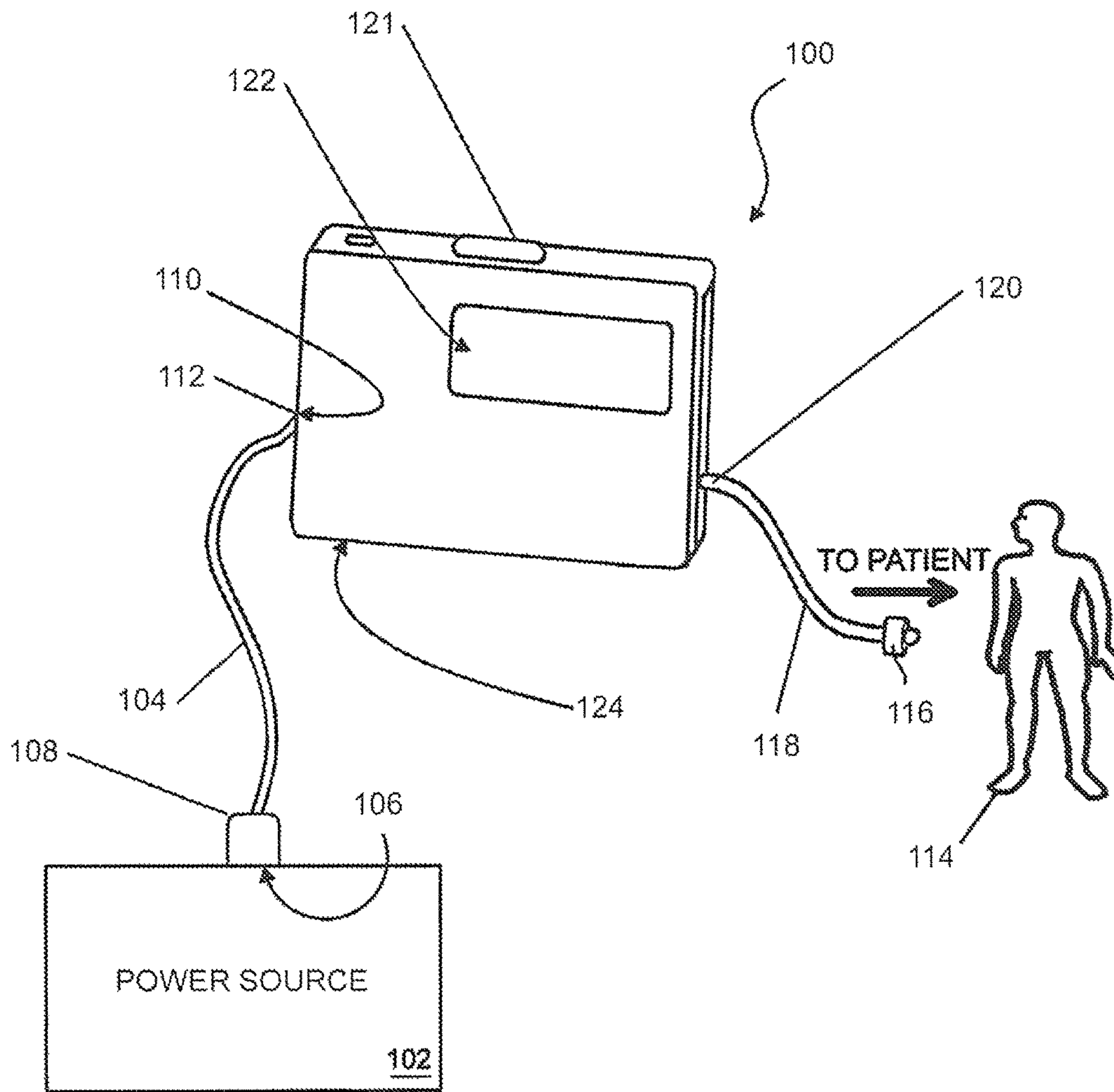


FIG. 1

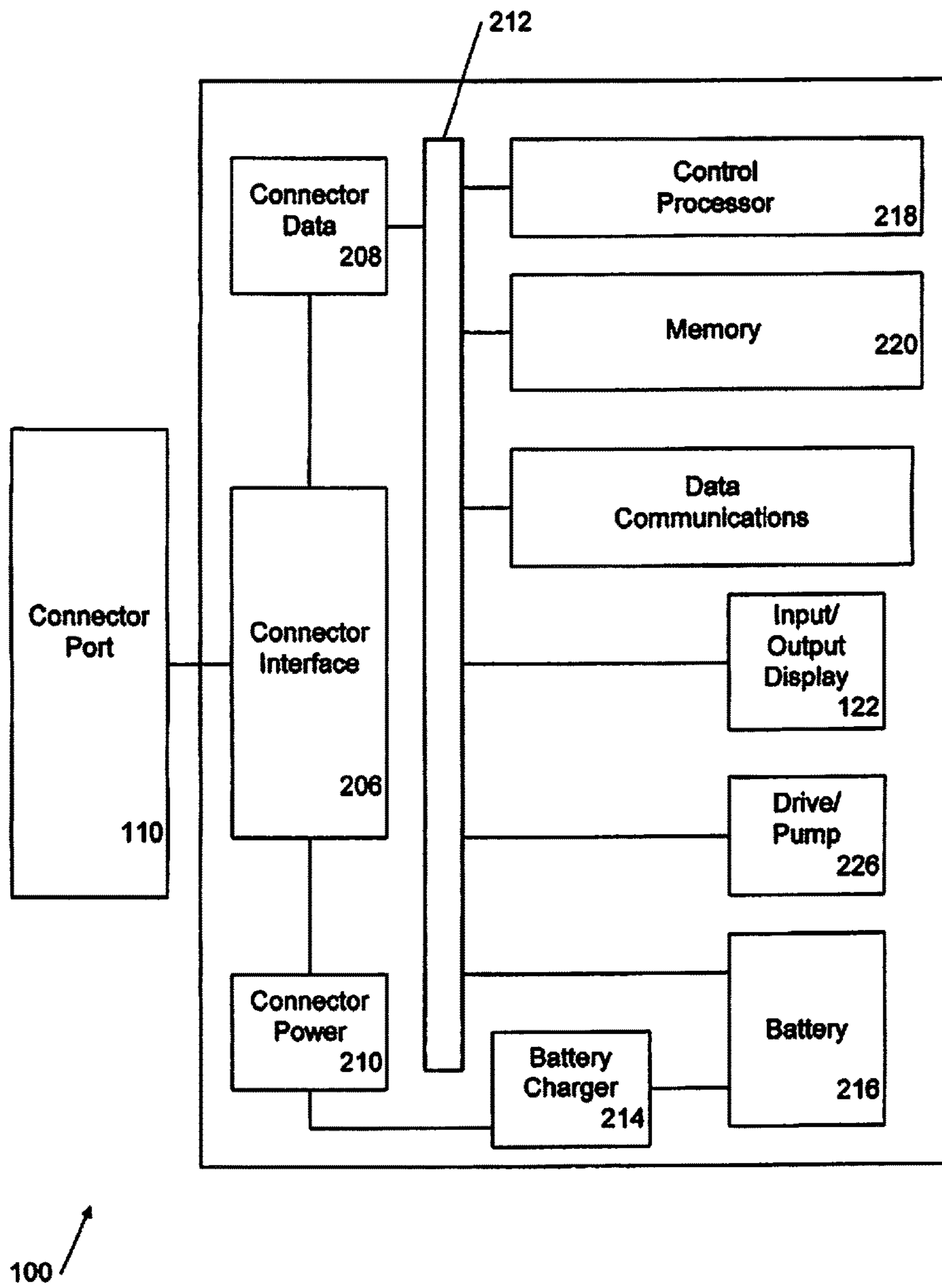


FIG. 2

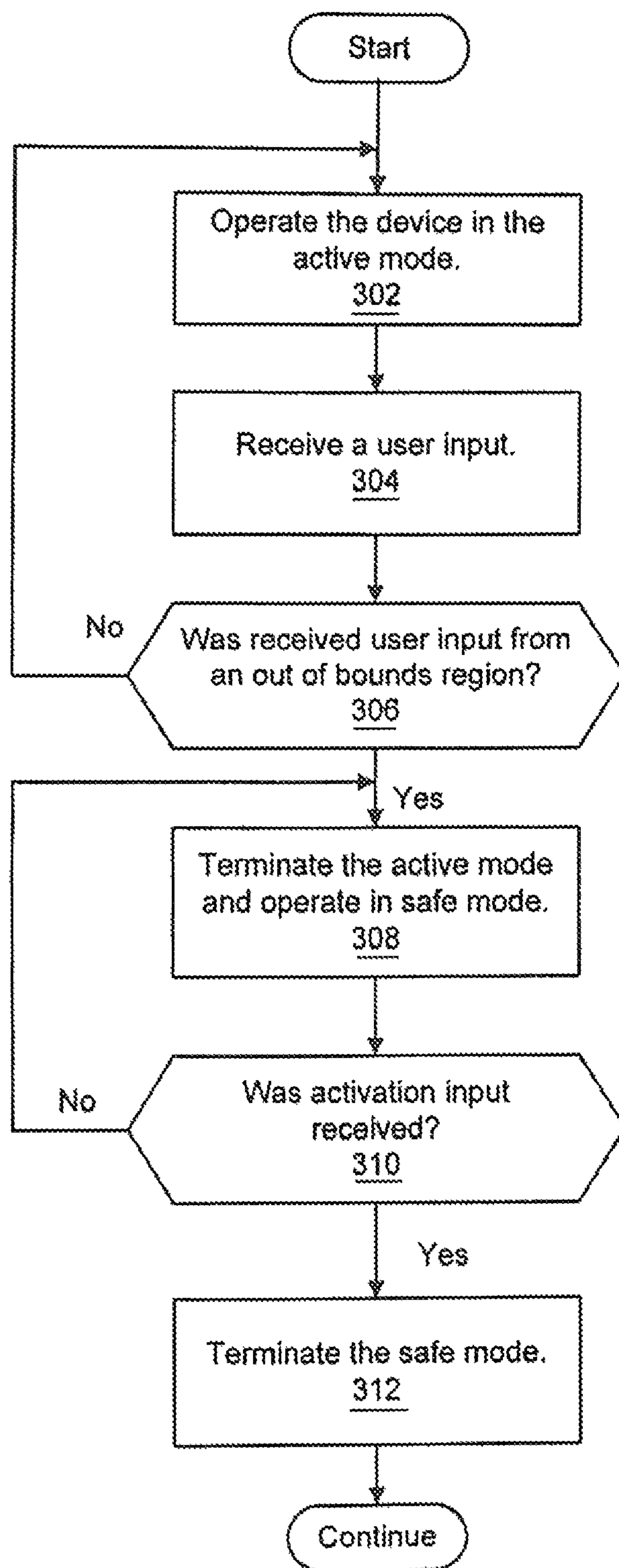


FIG. 3

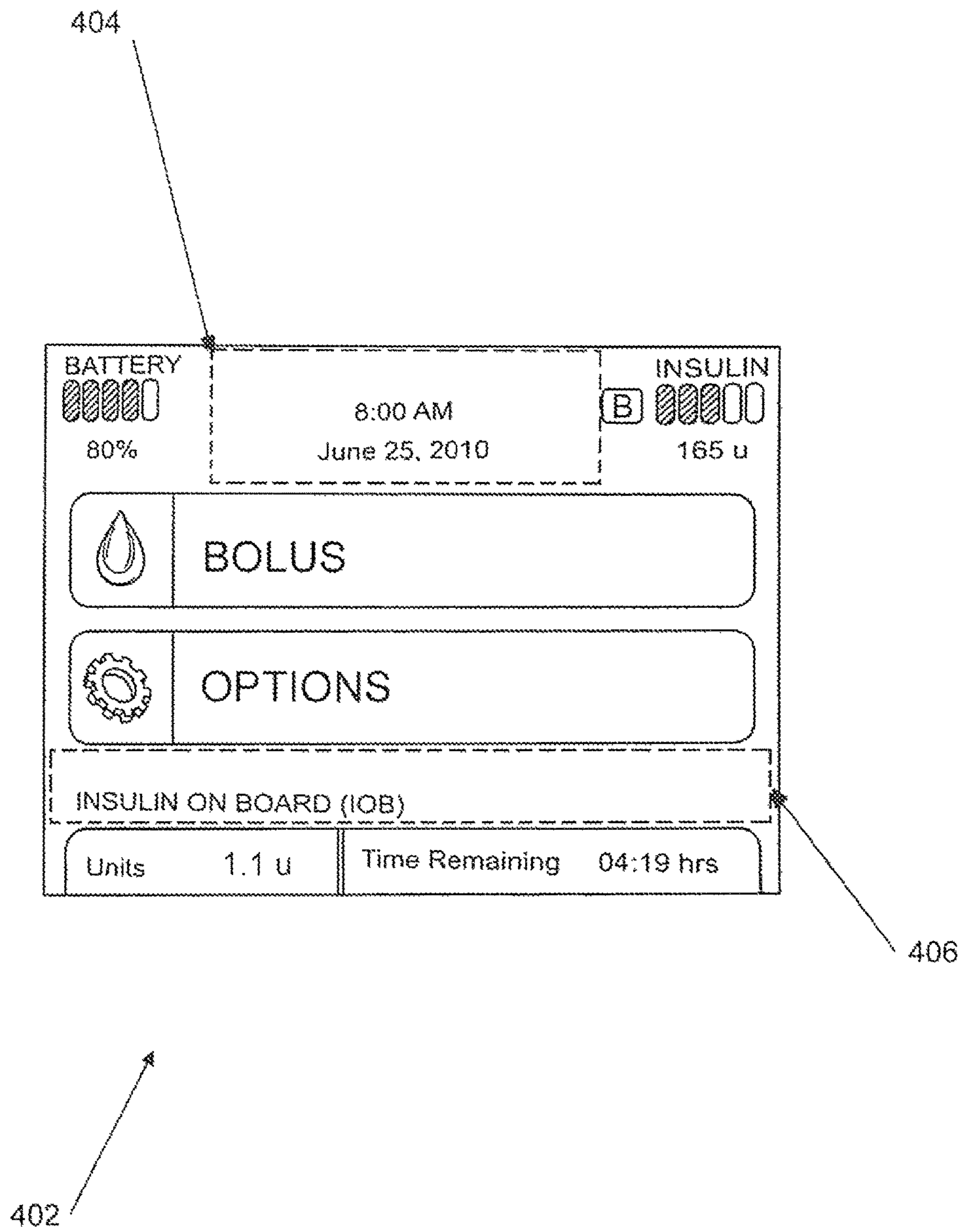
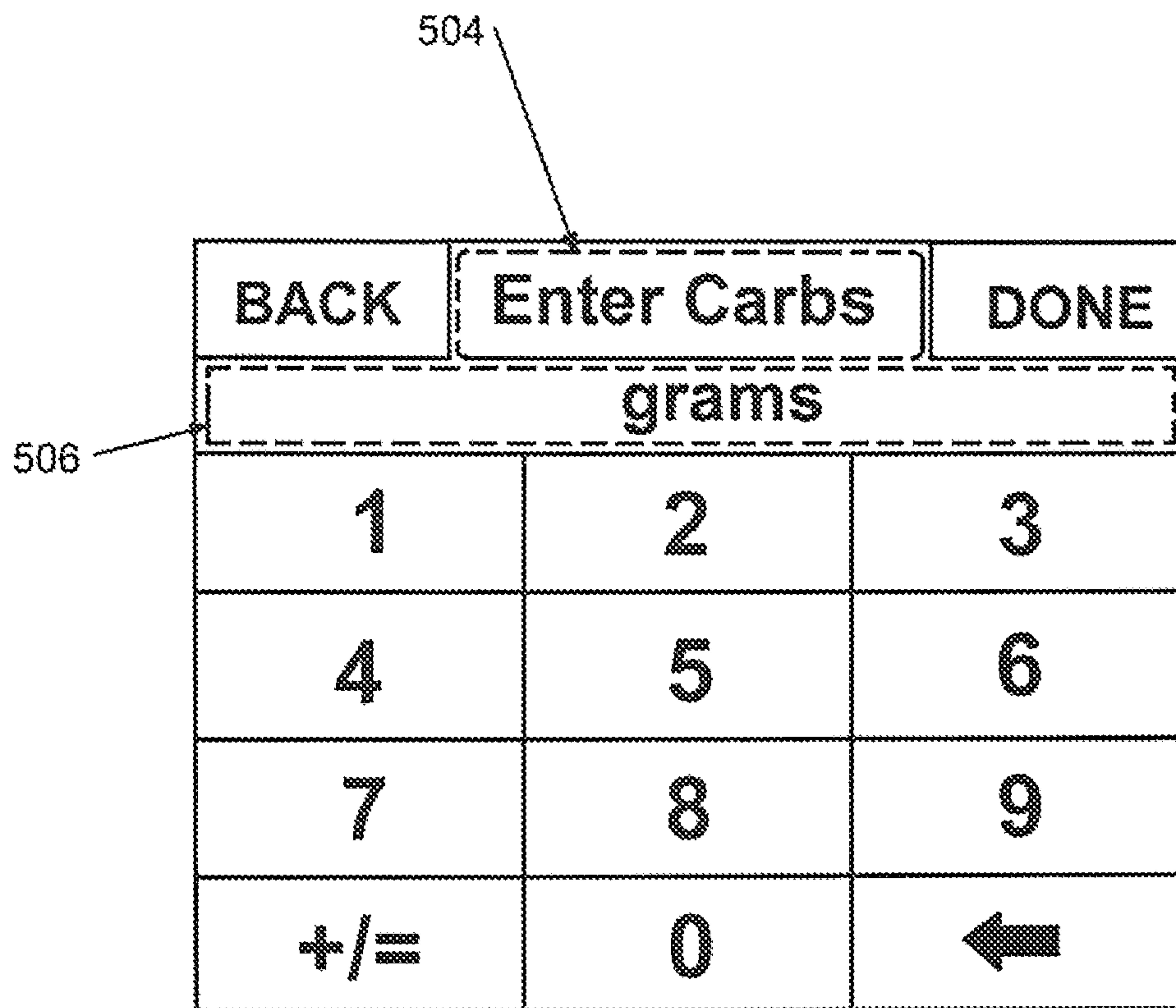


FIG. 4



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FIG. 5

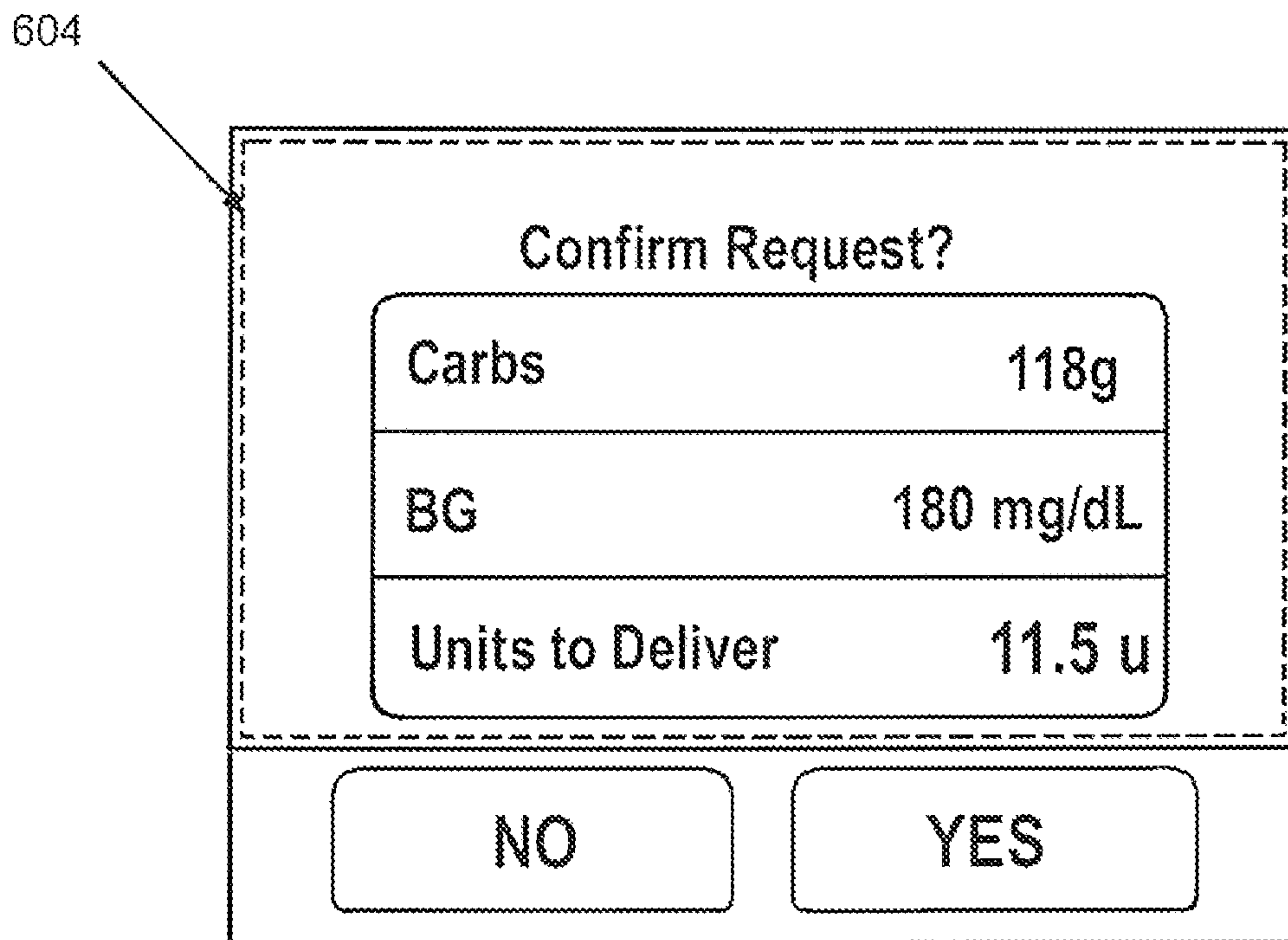
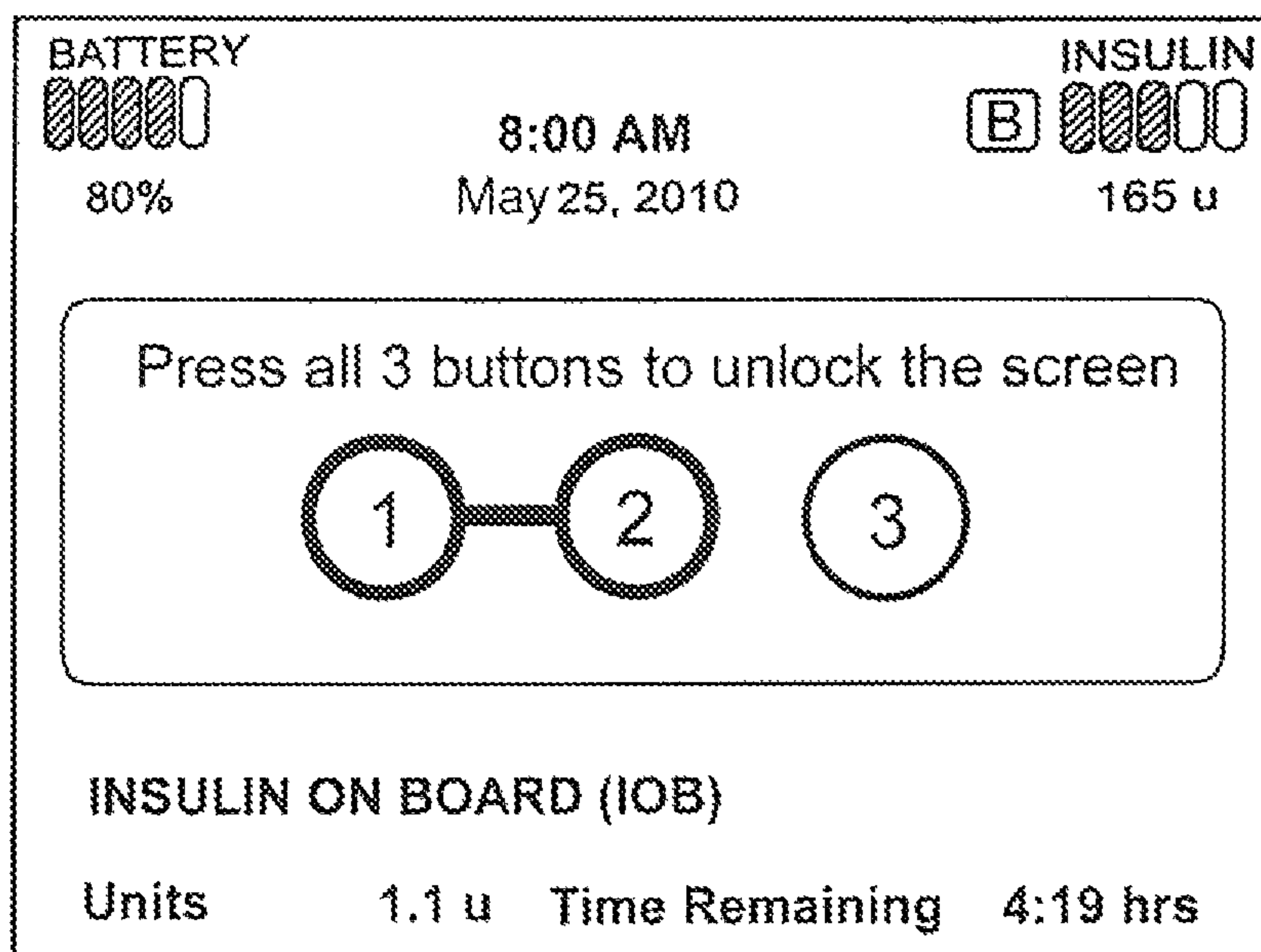


FIG. 6



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FIG. 7

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PREVENTING INADVERTENT CHANGES IN AMBULATORY MEDICAL DEVICES

RELATED APPLICATION

The present application claims the benefit of U.S. Provisional Application No. 61/656,997 filed Jun. 7, 2012, which is incorporated herein in its entirety by reference.

BACKGROUND

Portable ambulatory medical devices have proved useful for treating patients with medical conditions that require continuous monitoring and/or treatment. One example of such a portable ambulatory medical device is a device that involves the delivery of fluids. There are many applications in academic, industrial, and medical fields, as well as others, that involve devices capable of accurately and controllably delivering fluids, including liquids and gases, that have a beneficial effect when administered in known and controlled quantities. This is particularly true in the medical field, where treatments for many of patients include the administration of a known amount of a substance at predetermined intervals. For example, the treatment of diabetes involves just such a regimented dosage of medicaments such as insulin. In addition, diabetes is one of a few medical indications wherein patients routinely administer the medication to themselves by a subcutaneous modality, such as a hypodermic syringe injection or by an ambulatory infusion pump. As such, providing a patient with the means to safely, reliably, and comfortably administer required doses of medication such as, e.g., insulin, may be particularly important in order to facilitate patient compliance and accurate treatment of the condition.

Ambulatory insulin infusion pumps have been developed for the administration of insulin for those diagnosed with both type I and type II diabetes. Ambulatory insulin pumps are medical infusion devices used for the administration of insulin in the treatment of diabetes, and offer an alternative to multiple daily injections of insulin by an insulin syringe or an insulin pen. They also allow for continuous insulin therapy. In addition, some ambulatory insulin infusion devices can include data collection and storage mechanisms, which allow a diabetic person and/or a doctor to easily monitor and adjust insulin intake. The infusion device may be powered by a rechargeable battery that requires periodic recharging.

Some ambulatory medical devices include a touchscreen on which symbols may be displayed and from which inputs may be received for operation of the device. Other input mechanisms involve keyboards or hardware switches. In general, a series of display screens or windows are shown on a device display or on the device touchscreen, showing alphanumeric text and symbols, and providing menu screens through which the user can control operation of the device. User interaction, such as by touching the alphanumeric text and symbols, provides user input and facilitates navigation through the menu screens and selection of the device functions.

The phenomenon of unintended, inadvertent activation of portable devices is not an uncommon occurrence. Telephone calls accidentally placed via a mobile telephone through inadvertent activation have become a fact of modern life. Such accidental calls can be annoying and troublesome for a mobile telephone. In the case of a portable ambulatory medical device, such accidental activation can have serious consequences. In fact, in the case of portable ambulatory

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medical devices, any changes at all that are unintended or inadvertent may be problematic and even dangerous. For example, an untimely delivery of insulin, or delivery of an unexpectedly changed amount of insulin, or the absence of an expected dose, can have extremely deleterious results, and may even be dangerous to the user. User safety would be improved with a reduction in the likelihood of an accidental or unintended activation or deactivation of a portable ambulatory medical device.

SUMMARY

Disclosed herein are portable ambulatory medical devices and methods of operation that provide a reduced likelihood of inadvertent change in device operation. A device includes an active mode in which the device receives a user input at an input interface of the device and provides the received user input to a processor of the device. The active mode can be terminated and the device operated in a safe mode, in which the received user input is not provided to the processor and/or one or more device function is disabled, in response to determining that the received user input was received in an out of bounds region of the input interface. The safe mode is terminated in response to receiving a predetermined user input comprising an activation input. In some embodiments, the activation input can comprise selection of a wake display button or icon of the user interface, or may comprise a predetermined sequence of selected buttons or icons of the user interface.

In one embodiment, the activation input may be modified to require a timed pattern to wake the touchscreen. The pattern would require two or more presses that would be delivered in specified time windows, and if presses were detected outside of these windows, the sequence would be aborted.

In some embodiments, the portable device may include a user interface with control features such as buttons, switches or icons to control pumping and other functions, and the portable device may include a touchscreen on which are displayed alphanumeric text, symbols, menu screens, data, alerts, and other information. The device may show one or more screens or windows on the touchscreen through which device control inputs are received. For each device screen display, one or more regions of the display, and/or one or more buttons or switches, will be considered out of bounds for any intended control input. During an active mode of the device, when control inputs are received, any user interaction with an out of bounds region can cause the active mode to be suspended and the device will be in a safe mode of operation in which at least one of the device components is not operated. The device will remain in the safe mode until it receives an activation input before permitting continued active operation. The activation input may comprise a sequence of multiple inputs from the user via the touchscreen or a group of multiple inputs provided simultaneously, such as multiple simultaneous button presses. Failure to receive the activation input will result in the device remaining in the safe mode. The activation input may require the user to comply with activation sequence parameters as to both multiple symbol interactions and time between the multiple interactions. Requiring the predetermined activation sequence before resuming normal operation reduces the likelihood of accidental or unintended activation of the portable ambulatory medical device and improves user safety.

Other features and advantages of the present invention should be apparent from the following description of preferred embodiments that illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts a portable device according to an embodiment of the present invention that is coupled to a patient for infusing medication thereto.

FIG. 2 is a block diagram of circuitry and components for the portable medical device illustrated in FIG. 1.

FIG. 3 is a flow diagram showing operations of the device in FIG. 1.

FIG. 4 depicts a display screen with a home screen display showing out-of-bounds regions according to an embodiment of the present invention.

FIG. 5 depicts a display screen with a data entry screen display showing out-of-bounds regions according to an embodiment of the present invention.

FIG. 6 depicts a display screen with a confirmation screen display showing an out-of-bounds region according to an embodiment of the present invention.

FIG. 7 depicts a display screen with an unlock screen display.

The drawings illustrate embodiments of the technology and are not limiting. For clarity and ease of illustration, the drawings may not be made to scale and, in some instances, various aspects may be shown exaggerated or enlarged to facilitate an understanding of particular embodiments.

DETAILED DESCRIPTION

Disclosed herein are embodiments directed to a portable medical device having an interactive display screen, such as a touch screen, for control by the user, and having a connecting tube with an infusion port for administering medication to a patient.

FIG. 1 shows an electrically-powered portable device **100** that is coupled to a host power source **102**, such as a desktop or laptop computer, through a cable **104**. The cable may comprise, for example, a coupling through which both data and electrical energy are received at the portable device **100**. Examples of such combined power and data cables include a Universal Serial Bus (USB) connection, an IEEE 1499 connection, a “THUNDERBOLT” connection (i.e., from Apple, Inc., of Cupertino, Calif., USA), PCI Express, eSATA and Ethernet. The host power source **102** is a source of electrical energy and can be any type of computing device that includes a port **106** that receives a connector **108** of the cable **104**. The port of the host computing device may comprise, for example, a USB port, or IEEE 1499 port, or port for THUNDERBOLT, PCI Express, eSATA or Ethernet. A compatible connector port **110** of the portable device **100** is coupled to the cable **104** at an opposite end **112** of the cable. In a USB implementation, for example, the cable **104** is a USB cable and associated connections and ports may support one or more of USB version 1.1, 2.0, or 3.0 data transfer speeds.

The portable device **100** may be coupled to a patient **314** via an infusion port **116** and a connecting tube or cannula **118**. The connecting tube is coupled to the portable device **100** at a fluid dispensing port **120**. The portable device may include control features, such as buttons or switches **121** to receive user input and control pumping and other features, and may include a display screen **122** on which are displayed messages and alerts. The display **122** may comprise, for

example, a touchscreen on which user inputs may be received. A housing **124** of the portable device encloses internal components, such as fluid reservoirs, electrical components, battery, and the like. The portable device **100** illustrated in FIG. 1 comprises a portable medical device of the type worn by a patient **114** such that insulin fluid is delivered via the connecting tube **118** and the fluid dispensing port **120** by a delivery mechanism. Exemplary ambulatory medical devices and features include those, e.g., disclosed in U.S. patent application Ser. No. 13/557,163, U.S. patent application Ser. No. 12/714,299, U.S. patent application Ser. No. 12/538,018, U.S. Provisional Patent Application No. 61/655,883, U.S. Provisional Patent Application No. 61/656,967 and U.S. Pat. No. 8,287,495. Each of the aforementioned documents is hereby incorporated herein by reference in its entirety.

The portable device **100** can be coupled to a host power source such as a desktop or laptop computer, through a cable connected to the connector port **110**. The cable may comprise, for example, a coupling through which both data and electrical energy are received at the portable device **100**. Examples of such combined power and data cables include a Universal Serial Bus (USB) connection, an IEEE 1499 (FireWire) connection, a “THUNDERBOLT” connection (from Apple, Inc. of Cupertino, Calif., USA), PCI Express, eSATA and Ethernet.

The device **100** may also include a capability to operatively couple to one or more other devices via a wired or wireless (e.g., infrared, electronic, optical, etc.) link, locally or via a network, such as, e.g., a portable or non-portable medical device, a control unit, external monitor or display, a personal laptop, tablet or mainframe computer, or mobile communication device such as a smartphone or personal digital assistant (PDA). Such other devices may control or be controlled by device **100** and/or may otherwise communicate for the transfer of data including device parameters between or among device **100** and other device(s) for analysis of data (e.g., user data for physician review, device diagnostic data for troubleshooting or repair), programming, or other uses.

The portable device **100** may include control features such as buttons, panels, screens, and/or switches to control the device, or any combination of such control features. For example, the portable device **100** illustrated in FIG. 1 shows a touchscreen **122** on which can be displayed alphanumeric text, symbols, menu screens, data, alerts and the like for receiving control input. The portable device may include a processor with memory, wherein the processor executes program instructions to provide an operating system that supports programs that execute and provide the specified features. The touchscreen **122** may be interactive, wherein user input may be received such as by pressing the outer surface of the touchscreen. The touchscreen **122** may be configured to display menu screens or pages that allow the user to input data fields, e.g., select device parameters, so as to allow the program to produce a suggested delivery amount, rate, profile, and/or the like in an intuitive, manipulable, and/or graphic representation, thereby allowing the user to interact with the screen to shape the characteristic/form of the delivery amount, rate, and/or graphic delivery profile, e.g., by manipulating the delivery estimate or pattern displayed on the screen to effectuate the actual delivery.

Device parameters provided by the portable infusion device may be presented on the display screen **122** as any number of objects, including one or more numeric and/or alphanumeric values, a range, a value or range that is presented in the form of a drop-down menu, a toggle that can

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be adjusted by the user, a graphical representation (e.g., icon) or an animated graphic. For instance, in certain embodiments, the value is a range of values that are presented on a screen of the display as a toggle, wherein the toggle may be adjusted upwards or downwards by the user swiping a finger over the screen to select the appropriate value range, e.g. appropriate range of amounts of medication such as insulin to be delivered and/or the appropriate rate, time, or interval of medicament delivery. In certain instances, the values presented in the range may be adjusted by the processor (illustrated in FIG. 2). Other device parameters will be readily apparent to those skilled in the art.

The type of touch screen 122 may vary as desired to be useful for a particular application, such as LCD displays, LED displays, plasma displays, organic LED (OLED) displays, and the like. The touchscreen 122 may be implemented with a capacitance screen, a resistive screen, or other such display/input technology. The portable device 100 may additionally include a keyboard or other input device known in the art for data entry, which may be separate from the display.

FIG. 2 shows a block diagram of some of the components within the portable device 100 of FIG. 1. The portable device 100 includes a power management system 202 that is connected to the connector port 110 that receives a combined data/power cable, such as the USB cable 104 illustrated in FIG. 1. That is, the cable 104 has the capability of simultaneously providing electrical energy for charging and data transmission for communications. A connector interlace 206 supports data exchange and receives electrical power through the connector port 110, and controls a connector data element 208 and a connector power element 210. The device may be powered by battery power in place of or in addition to the connector interface. The connector interface 206 passes data communications front the connector port 110 through the connector data element 208 to a system bus 212. The connector interface 206 passes electrical power from the connector port 110 through the connector power element 210 to a battery charger 214, which in turn is coupled to a battery 216 and which recharges the battery. In one embodiment, the connector data element 208 is implemented in the FIG. 2 device with a USB Isolation Chip ADUM4160 product from Analog Devices, Inc. of Norwood, Mass., USA, and the connector power element 210 is implemented in the FIG. 2 device with a USB Power Isolation Chip LT3573 product from Linear Technology Corporation of Milpitas, Calif., USA. Those skilled in the art will be aware of alternative suitable devices.

A control processor 218 is connected to the system bus 212 and receives the data communications from the connector data element 208 for processing. The control processor controls operation of the various elements of the portable device 100 that are connected to the system bus. The control processor operates according to mode instructions that may be stored in device memory 220.

The portable device 100 operates under control of the processor 218 so as to include at least two modes of operation, comprising an active mode and a safe mode. The active mode is an operating mode in which multiple device components are operated. The safe mode is an operating mode in which at least one device component is deactivated and is not operated. For example, in the active mode, the touchscreen display 122 and the pump 226 may be operated, whereas, in the safe mode, the pump may be deactivated and not operated.

FIG. 3 is a flowchart that illustrates operation of the device. In the first operation, indicated by the flowchart box

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302, the processor operates the device in the active mode, in which a user may enter input at the input interface of the device. At the next operation, at box 304, a user input is received at the input interface. The user input may comprise an intentional input at the device, such as a user interaction with the touchscreen, or the user input may comprise an accidental interaction with the touchscreen. The user input may optionally comprise making an affirmative action to place the device into safe mode. For example, the affirmative action may comprise pressing a physical button or switch on the device or on a smart phone that turns off the display. This option useful, for example, for placing the device in the safe mode prior to placing the device in a pocket or purse. In the next operation, indicated by the decision box 306, the device processor determines if the received user input was at an out of bounds region of the display. For each display screen during operation of the device, predetermined areas of the display screen will comprise an active area and other predetermined areas will comprise an out of bounds region. For example, FIGS. 4, 5, and 6 illustrate display screens with the respective predetermined out of bounds regions indicated. FIG. 4 shows a home screen display 402 with two rectangular out-of-bounds regions 404, 406 identified. FIG. 5 shows a data entry screen display 502 with two out-of-bounds regions 504, 506 identified. FIG. 6 shows confirmation screen display 602 with a relatively large rectangular out-of-bounds region 604 identified. Any single button input or predetermined plurality of inputs received in any of the out-of-bounds regions during a respective active operation while the corresponding screen is displayed will result in the device entering the safe mode.

Returning to the flow diagram of FIG. 3, if the input was at an out-of-bounds region, an affirmative outcome at box 306, then the processor proceeds to the operation of box 308, terminating the active mode of operation and initiating operation of the device in the safe mode. If the input was not received from an out of bounds region, a negative outcome at box 308, then the device continues to operate in the active mode and additional input may be received, as indicated by the return to operation at box 302. The processor will deactivate at least one component of the device while in the safe mode of operation. For example, the processor may deactivate the pump of the device while it is in the safe mode, to ensure that no accidental delivery of insulin is initiated. The processor may disable changes to settings in memory, to ensure that bolus settings and the like are not changed during the safe mode.

While in the safe mode of operation, the processor waits for an input comprising an activation input. If an activation input is received, an affirmative outcome at box 310, then the process terminates the safe mode of operation at step 312. Typically, the processor will return to the active mode of operation, but other modes may be initiated, as desired. For example, a power saving mode might be preferred. If no activation input is received, a negative outcome at box 310, then the processor maintains the device in the safe mode.

The activation input may comprise selection of a wake display button or icon of the user interface. Alternatively, the activation input may comprise predetermined sequence of selected buttons or icons of the user interface. For example, the sequence may comprise discrete selection of predetermined buttons on the touchscreen display. In another alternative, the predetermined sequence may comprise a sequence of predetermined button selections separated by predetermined amounts of time. For example, the predetermined sequence may involve button selections that are separated in time by no more than an activation time value.

The activation time value may have a value of, for example, no more than two seconds. If the time elapsed between any two display button selections is greater than two seconds, then the processor will consider the inputs to be random or accidental, and the processor will remain in the safe mode. In a further embodiment, the activation input can comprise a user swiping a touchscreen in a predetermined pattern or shape.

FIG. 7 shows an example of an unlock screen 702 that is displayed on the touchscreen of the device as part of the safe mode operation. That is, when the device enters the safe mode, the processor produces an unlock screen display and awaits the activation input from that screen. For example, in FIG. 7, the three buttons labeled “1”, “2”, and “3” must be pressed in proper (numerical) sequence, separated in time by no more than an activation time value.

In some embodiments, the safe mode can also be entered at the end of one or more predetermined sequences of user interaction with the pump, such as a sequence after which a user is likely to be finished interacting with a pump for a period of time. For example, after a user programs a bolus and executes a deliver command, the pump can automatically enter a safe mode in which the screen is locked. This would prevent the user from inadvertently cancelling or modifying the bolus or otherwise interacting with the device in an unintended fashion during the bolus delivery while, for example, placing the pump back against the user’s body. Pump operation can therefore subsequently be modified during delivery of the bolus only by unlocking the screen as described above. In one embodiment, the pump can remain locked after the bolus is delivered and until the screen is unlocked.

Although the aforementioned description specifically describes a portable medical device for administering insulin to a patient, it should be understood that such a device is only one embodiment of the invention. The device can also include any portable device having a display and a processor. For example, the device can include a mobile computing device, such as a Smartphone. In one embodiment, such a mobile computing device can be used as a remote control to wirelessly control operations of medical devices as disclosed herein. Alternatively, medical devices as disclosed herein can be controlled remotely with a dedicated remote control specifically designed for use with the medical device.

The methods, systems, and devices discussed above are intended merely to be examples. Various embodiments may omit, substitute, or add various procedures or components as appropriate. For example, it should be appreciated that, in alternative embodiments, the methods may be performed in an order different from that described, and various steps may be added, omitted, or combined. Also, features described with respect to certain embodiments may be combined in various other embodiments. Different aspects and elements of the embodiments may be combined in a similar manner. Also, it should be emphasized that technology evolves and, thus, many of the elements are examples and should not be interpreted to limit the scope of the invention.

Specific details are given in this description to provide a thorough understanding of the embodiments. Nevertheless, it will be understood by one of ordinary skill in the art that the embodiments may be practiced without these specific details. For example, well-known circuits, processes, algorithms, structures, and techniques have been shown without unnecessary detail in order to avoid obscuring the embodiments. Further, the headings provided herein are intended merely to aid in the clarity of the descriptions of various embodiments, and should not be construed as limiting the

scope of the invention or the functionality of any part of the invention. For example, certain methods or components may be implemented as part of other methods or components, even though they are described under different headings.

It is noted that embodiments may have been described as a process that is depicted as a flow diagram or block diagram. Although each diagram may describe the process as a sequential series of operations, many of the operations can be performed in parallel or concurrently. In addition, the order of the operations may be rearranged. A process may have additional steps not included in the figures. Each operation of a process is performed or executed by the processor of the device.

The description above has been provided in terms of presently preferred embodiments so that an understanding of the present invention can be conveyed. There are, however, many configurations and techniques for data management systems that were not specifically described herein, but with which the present invention is applicable. The present invention should therefore not be seen as limited to the particular embodiments described herein, but rather, it should be understood that the present invention has wide applicability with respect to data management generally. All modifications, variations, or equivalent arrangements and implementations that are within the scope of the attached claims should therefore be considered within the scope of the invention.

The invention claimed is:

1. A portable ambulatory infusion system, comprising:
 - a housing;
 - a delivery mechanism at least partially contained within the housing and adapted to facilitate delivery of fluid to a user;
 - a user interface comprising a touchscreen, the touchscreen adapted to display a plurality of input screens and receive touch input from a user on the plurality of input screens;
 - a memory adapted to store operating parameters and settings relating to use of the delivery mechanism; and
 - a processor disposed in the housing and configured to control operation of the portable ambulatory infusion system in an active mode and a safe mode, wherein in the safe mode the processor disables at least one ambulatory infusion system operation that is active in the active mode, the processor further configured to:
 - define one or more active areas on the plurality of input screens configured to receive touch input with selectable icons from the user for the ambulatory infusion system operation;
 - define one or more out of bounds regions associated with corresponding input screens in the memory, wherein the one or more out of bounds regions displayed on the corresponding input screen are defined as areas of the corresponding input screen that are not the one or more active areas associated with the selectable icons configured to receive control input from the user on the corresponding input screen;
 - identify a touch input on the touchscreen on one of the plurality of input screens that is in at least one of the one or more out of bounds regions of the corresponding input screen while the portable ambulatory infusion system operation is in the active mode;
 - suspend the ambulatory infusion system operation in the active mode and place the ambulatory infusion system operation in the safe mode in response to the touch input received in the at least one of the one or

more out of bounds regions that are not the one or more active areas associated with the selectable icons, including disabling at least one of the one or more active areas on the corresponding input screen from receiving touch input.

2. The portable ambulatory infusion system of claim 1, wherein the processor is further configured to terminate the safe mode and return to the active mode upon identifying a touch input at the touchscreen as a predetermined activation input.

3. The portable ambulatory infusion system of claim 2, wherein the predetermined activation input comprises selection of a wake display icon on the user interface.

4. The portable ambulatory infusion system of claim 2, wherein the predetermined activation input comprises a predetermined sequence of selected icons on the user interface.

5. The portable ambulatory infusion system of claim 4, wherein the predetermined sequence comprises a series of distinct touch inputs each separated by no more than a maximum predetermined amount of time.

6. The portable ambulatory infusion system of claim 1, wherein the processor is further configured to display an unlock screen on the touchscreen after safe mode is entered.

7. The portable ambulatory infusion system of claim 1, wherein the processor defines one or more of the out of bounds regions for the plurality of input screens, each of the one or more out of bounds regions customized for the corresponding input screen.

8. The portable ambulatory infusion system of claim 1, wherein the at least one ambulatory infusion system operation that is disabled in the safe mode is an operation of the delivery of the fluid by the delivery mechanism.

9. The portable ambulatory infusion system of claim 1, wherein the at least one ambulatory infusion system operation that is disabled in the safe mode is alteration of the operating parameters and settings of the portable ambulatory infusion system stored in the memory.

10. The portable ambulatory infusion system of claim 1, wherein the touchscreen is disposed on the housing.

11. The portable ambulatory infusion system of claim 1, wherein the touchscreen is disposed on a separate device remote from the housing and the processor is adapted to receive information related to the touch input on the touchscreen wirelessly from the separate device.

12. A portable ambulatory infusion pump, comprising:
a processor that controls operation of the portable ambulatory infusion pump in a plurality of operating modes that include an active mode in which multiple ambulatory infusion pump components are operated and a safe mode in which at least one ambulatory infusion pump component is deactivated and not operated;
an input interface through which the processor receives user input, the input interface comprising a touchscreen

adapted to receive touch input from a user, wherein the processor defines one or more active areas of the input interface configured to receive the touch input for portable ambulatory infusion pump operation;

wherein the processor defines out of bounds regions associated with the input interface in the memory and each of the out of bounds regions of the input interface being a non-active area of the input interface that is not configured to receive touch input from the user for portable ambulatory infusion pump operation, and

wherein the processor terminates the active mode and operates the ambulatory infusion pump in the safe mode in response to determining that a received touch input was an accidental interaction with the input interface received in one of the out of bounds regions of the input interface defined as one of the non-active areas, and

wherein operating the portable ambulatory infusion pump in the safe mode in response to the user input in the one of the out of bounds regions defined as one of the non-active areas includes locking the touchscreen from receiving touch input at the one or more active areas.

13. The portable ambulatory infusion pump of claim 12, wherein the processor terminates the safe mode in response to receiving an activation user input through the input interface comprising a predetermined activation input.

14. The portable ambulatory infusion pump of claim 13, wherein the activation input comprises selection of a wake display icon of the input interface.

15. The portable ambulatory infusion pump of claim 13, wherein the activation input comprises a predetermined sequence of selected icons on the input interface.

16. The portable ambulatory infusion pump of claim 15, wherein the predetermined sequence comprises a series of distinct inputs each separated by no more than a maximum predetermined amount of time.

17. The portable ambulatory infusion pump of claim 13, wherein the processor resumes operating the device in the active mode in response to terminating the safe mode.

18. The portable ambulatory infusion pump of claim 12, wherein the processor is further configured to display an unlock screen on the input interface after safe mode is entered.

19. The portable ambulatory infusion pump of claim 12, wherein the at least one ambulatory infusion pump component that is deactivated in the safe mode is a delivery mechanism for delivering fluid to a user.

20. The portable ambulatory infusion pump of claim 12, wherein the at least one ambulatory infusion pump component that is deactivated in the safe mode is a memory for storing alteration of operating parameters and settings.